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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/561,545 | 12/19/2005 | Alan David Borthwick | PB60320USW | 9778 |
| 23347 7590 06/20/2007 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 | | | EXAMINER | |
| | | | CHUNG, SUSANNAH LEE | |
| FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398 | | ART UNIT | PAPER NUMBER | |
| • | | | 1626 | |
| • | | • | | |
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| | | • | 06/20/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | A 1: 4: Nt - | A = 1: 4/ - \ | | | |
|--|--|------------------|--|--|--|
| • | Application No. | Applicant(s) | | | |
| Office Action Commence | 10/561,545 | BORTHWICK ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Susannah Chung | 1626 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1) | action is non-final. nce except for formal matters, pro | • | | | |
| Disposition of Claims | | • | | | |
| 4) ☐ Claim(s) 1-11 is/are pending in the application. 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-8 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | • | | | |
| 12) △ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) △ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/19/2005. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | |

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DETAILED ACTION

Claims 1-11 are pending in the instant application.

Priority

This application is a 371 of PCT/EP04/06592, filed 6/17/2004.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. 0314299.9 filed in the UK Patent Office on 06/19/2003, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

Response to Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 05/14/2007 is acknowledged. Specially, the election of species of the compound of Example 1, on page 33, also known as 4-{(3S)-3-[{[(1E)-2-(5-chloro-2-thienyl)-1-propen-1-yl]sulfonyl}-(cyclopropylmethyl)amino]-2-oxo-1-pyrrolidinyl}-3-fluoro-N,N-dimethylbenzamide,

The traversal is on the ground that the claims have unity of invention. Examiner respectfully disagrees. The special technical feature of the claims is as indicated in the previous office action. It was found to not define a contribution over the prior art and as such unity of

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invention was broken. Therefore the requirement is still deemed proper and is therefore maintained.

Scope of the Elected Invention

Claims 1-11 are pending in this application.

The scope of the elected subject matter that will be examined and searched is as follows:

Compounds of formula (I),

, depicted in claim 1, page 41, wherein:

X is phenyl.

Scope of Withdrawn Subject Matter

Claims 9-11 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

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Compounds of formula (I)

, depicted in claim 1, page 41, wherein:

X is not phenyl.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Smallheer, et al (U.S. Pub. No. 2003-429461, now U.S. Pat. No. 7,157,470 (Pat `470)).

Applicants claims of substituted indole compounds relate to compounds found in Pat. '470. Smallheer discloses compounds that anticipate the instantly claimed genus and species wherein: X is phenyl, Y is NRaRb, RaRb is together with N a heterocyclic ring, R1 is naphthalene, R2 is alkyl and as stated in the claims (see Smallheer et al., compounds in Column 51-53). In particular, see the compounds in Column 52, lines 20-25, 6-chloro-N-[2-oxo-1-piperidinyl)phenyl]-3-pyrrolidinyl]-2-naphthalenesulfonamide, CAS RN 641612-43-3,

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 , and the compound in Column 52,

lines 60-65, 6-chloro-N-[2-oxo-1-pyridinyl)phenyl]-3-pyrrolidinyl]-2-naphthalenesulfonamide,

CAS RN 641612-44-4

on the instant claims.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "derivative" of the compounds of Claim 1 are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1-3 and 5-8.

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Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "use in therapy" is not defined in the specification so as to know the disorders to be treated or used in therapy by this compound. A possible alternative to this language is to use the term "pharmaceutically acceptable salt" found on page 9 of the specification.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 and 5-8 are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claims 1-3 and 5-8 are drawn to the derivatives of compounds in Claim 1. However, the "derivative" of the compounds of Claim 1 are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claim is indefinite.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC

REBECCA ANDERSON PATENT EXAMINER

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Date: 18 June 2007